

5/23/06



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

PIEDMONT REGIONAL OFFICE

4949-A Cox Road, Glen Allen, Virginia 23060

(804) 527-5020 Fax (804) 527-5106

www.deq.virginia.gov

L. Preston Bryant, Jr.
Secretary of Natural Resources

David K. Paylor
Director

Gerard Seeley, Jr.
Regional Director

June 22, 2006

Central Virginia Health Network
Attn: Mrs. Scarlett Mitchell
2521 Brittons Hill Road
Richmond, VA 23230

Re: True Minor Inspection Report
Registration No: 52111

Dear Mrs. Mitchell:

Enclosed, please find a copy of the inspection report generated from the on-site inspection conducted on May 23, 2006. Please review the report in its entirety.

The report is based on observations made during the onsite inspection and information reviewed in support of report generation. The existence of a report indicating compliance with applicable requirements listed in the report is not verification that your operation is in compliance with all applicable provisions of the Regulations for the Control and Abatement of Air Pollution.

Please consider the following information regarding the minimum abator temperature item. During operation of the ETO sterilizers, the facility indicates that the temperatures reached are proximate to 400° F. The facility provided additional information in narrative and in a figure titled: 'ETO Conversion Performance' indicating the optimum abator efficiency temperature, based on manufacturer's specifications, is approximately 280 degrees F.

With the current Permit, the facility is required to demonstrate compliance with the minimum 400° F for both abators. Should the facility consider that a minimum temperature, other than 400° F, be incorporated into the permit to reflect manufacturer's specifications and/or enhanced removal efficiency, the facility is requested to submit a Form 7 to Air Permitting within 30 days of receipt of this letter. The Form 7 can be downloaded from the following website <http://www.deq.virginia.gov/air/justforms.html>. The completed Form 7 should then be sent to the following address:

James Kyle
Air Permit Manager
VADEQ-Piedmont Regional Office
4949-A Cox Road
Glen Allen, VA 23060

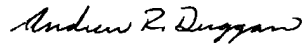
If the facility chooses otherwise (i.e. not to submit a Form 7 and operate with the current abator temperature requirement—minimum 400° F) the facility is required to demonstrate continuous compliance with said minimum temperature requirement for both abators when the units are in operation. Please let me know, if the facility intends to seek a permit revision. My contact information is herein provided.

Please note, Regional staff will evaluate all sources for compliance with the regulations on a continuous basis.

VADEQ would like to thank the Central Virginia Health Network for the facility's cooperation, courtesy, and professionalism during the on-site inspection.

If you have any questions or comments regarding this information, please do not hesitate to contact me at (804) 527-5095.

Sincerely,



Andrew Duggan
Enforcement and Compliance Specialist, Sr.

cc: Compliance Files
Mr. Daniel Gaidos (VADEQ-PRO Air Permitting)

Attachment(s): Inspection Report 06/13/06

Commonwealth of Virginia

Registration No: 52111 AFS Plant ID: 087-00562
Plant Name: Central Virginia Health Network Classification: True Minor
Address: 2521 Brittons Hill Rd Region: PRO
Report No: 235834

AIR INSPECTION REPORT

Inspection Date: 05/23/06 Contact Name: Scarlett Mitchell
Type: PCE With Site Visit Contact Phone No: (804) 545-4260
Inspector: Andrew R Duggan Air Program Subpart
Inspection Result: In Compliance NSR
Reason: SIP
Conduct On-Site Inspection

****Additional Information is Attached******Inspector Comments:**

PURPOSE: Central Virginia Health Network (Facility) operates as a medical equipment sterilizing facility. The facility is located at 2521 Brittons Hill Road in Richmond, Virginia. An announced site visit was conducted on 05/23/06 to determine compliance with the facility's applicable requirements. This site visit was prompted by the transfer of 3 Ethylene Oxide Steam Sterilizers (ETO) from St. Mary's Hospital (Registration No. 50412) to the Facility.

PROCESS DESCRIPTION: The facility sterilizes medical equipment according to material specifications (residence times / temperature / disinfecting agents). During the inspection, the facility was at the beginning stages of ETO sterilizer operations. The 3 ETO steam sterilizers operated at the facility have abators as air pollution control devices. Abator temperatures are continuously monitored by chart recorders.

PERMITTING BACKGROUND: The facility currently operates under a New Source Review (NSR) Permit dated June 10, 2005.

REGULATORY BACKGROUND: The facility is a true minor source. Current applicable regulatory requirements (A/Rs) include the following:

- NSR Permit dated June 10, 2005

COMPLIANCE BACKGROUND: This is the first on-site Air Inspection conducted at this facility. The facility has no recent (previous ten years) compliance or enforcement issues.

PRECEDING 12 MONTHS DATA: 'Initial Notification' (January, 2006), 'Initial Notification' (May, 2006). Reviews of these reports resulted in Compliance Determinations of 'In Compliance'.

INSPECTION NOTES: The Inspector arrived on-site at 12:00 PM and conducted a pre-inspection meeting with Mr. Stephen Dorfman (3M Health Care Field Service Representative). The Inspector conducted a walk through of the facility premises. After the walk-through, a records-review was conducted, followed-up by a post-inspection meeting with Mrs. Scarlett Mitchell (Administrative Director, Offsite Sterile Processing). The inspection was concluded by the Inspector leaving the premises at 2:00 PM.

RECOMMENDATIONS:

Facility is operating in compliance with the A/Rs.

ATTACHMENTS:

- E-mail (06/09/06).



Commonwealth of Virginia

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AFS Plant ID: 087-00562

Plant Name: Central Virginia Health Network

Classification: True Minor

Address: 2521 Brittons Hill Rd

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Report No: 235834

Inspector Comments:

- Technical Specification Sheet: 'Donaldson Model 50 SCFM Abator'
- ETO Conversion Performance Graph
- Chart Recorder Information
- Sterilization Record (05/18/06)
- Sterilization Record (05/19/06)
- Document Certification Form
- Inservice Attendance Sheet
- Mandatory In Service-ETO
- Customer Service Orders (7)

Andrew R. Duggan

Charles L. Turner

Inspector's Electronic Signature

Approval Date: Jun 15, 2006

Manager's Electronic Signature

Approval Date: Jun 20, 2006



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INSPECTION CHECKLIST

Permit Date or Basis	#	Requirement Narrative	Observation	Compliance Status
06-10-05	4	Emission Controls - The ethylene oxide sterilizers shall be equipped with an interlock system to prevent ethylene oxide venting to an abater prior to the abater's reaching a minimum temperature of 280 oF. (9 VAC 5-50-260)	The equipment was observed to be in place and in operation during the on-site inspection. The abatators have double solenoids so that the abatators will be by-passed should the minimum temperature not be reached. The ethylene oxide would then be vented to outside. In addition, if the abator undergoes a malfunction, the ethylene oxide will be diverted from the abatators and vented to the outside.	In Compliance
06-10-05	5	Throughput - The three ethylene oxide sterilizers combined shall not sterilize more than 2340 cycles per year, calculated as the sum of each consecutive 12 month period. (9 VAC 5-80-1180)	The facility complies with this permit condition by recording the daily number of cycles in a notebook. From this book, the daily recordings are transcribed into a spreadsheet on a monthly basis. The facility maintains a 'Sterilization Record' for each batch that enters the ETO sterilizers (See Attachments). The facility provided copies of records upon request.	In Compliance



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INSPECTION CHECKLIST

Permit Date or Basis	#	Requirement Narrative	Observation	Compliance Status
06-10-05	1	Equipment List - Equipment to be constructed at this facility consists of: - 3M Model 4XL Ethylene Oxide Sterilizer and Model 20 Aeration Cabinet rated at 0.22 lbs of sterilization compound per cycle - 3M Model 4XL Ethylene Oxide Sterilizer and Model XL Aeration Cabinet rated at 0.22 lbs of sterilization compound per cycle - 3M Model 4XL Ethylene Oxide Sterilizer and Model XL Aeration Cabinet rated at 0.22 lbs of sterilization compound per cycle (9 VAC 5-80-1180 D.3.)	The equipment was observed to be in place and in operation during the on-site inspection. According to the facility, the Model 20 Aeration Cabinet was disconnected at the time of the inspection and will be removed from the site. The Model 20 Aeration Cabinet was on-site as a back-up. The three (3) 3M Model 4XL ETOs have internal aeration cabinets; therefore, they do not need the external aeration cabinets. The facility was advised to discuss this item with VADEQ-Air Permitting in order that the equipment at the facility during future inspections is consistent with the equipment list in the permit.	In Compliance
06-10-05	2	Emission Controls - Ethylene oxide emissions from the three ethylene oxide sterilizers shall be controlled by two abaters. The abaters shall be provided with adequate access for inspection.	The equipment was observed to be in place and in operation during the on-site inspection. According to the Technical Specification Sheet for the abator (See Attachment),	In Compliance



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		(9 VAC 5-50-260)	the abator system is a control device for removing ethylene oxide through a chemical conversion of ethylene oxide to carbon dioxide and water. Two (2) abators were present on-site and are each designed for a maximum of two (2) ETO sterilizers each.	
06-10-05	3	Emission Controls - The operating temperature of the two abaters shall be maintained at a minimum of 400 F when the unit is in operation. The abaters shall be equipped with a thermostat to maintain the minimum temperature. In addition the abaters shall be equipped with continuous temperature sensors to indicate the temperatures of the abaters. The temperature of the abaters shall be continuously recorded when in operation. (9 VAC 5-50-260)	Temperature readings from the Honeywell chart recorder for the two abators were unavailable during the on-site inspection. The facility noted that indicator lights indicate when the appropriate temperature has been reached. The indicator lights were observed to be in operating condition. The Inspector advised the facility to take action as necessary to ensure compliance with this permit condition. The facility responded to VADEQ (See Attachment) within the requested timeline indicating and providing	In Compliance



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supporting documentation that the chart recorders are on-line at this time and are working properly. There are two chart recorders--one recording temperatures for ETO sterilizer 1 and 2, and the second recording temperatures for ETO sterilizer 3. During operation of the ETO sterilizers, the facility indicates that the temperatures reached are proximate to 400 degrees F. The facility provided additional information (See Attachment) indicating the optimum abator efficiency temperature is approximately 280 degrees F. The cover letter to this inspection report requests the facility to submit a Form 7 to Air Permitting should the facility consider a revision to the minimum abator temperature necessary for purposes of compliance.



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Permit Date or Basis	#	Requirement Narrative	Observation	Compliance Status
06-10-05	7	<p>On Site Records - The permittee shall maintain records of emission data and operating parameters as necessary to demonstrate compliance with this permit. The content and format of such records shall be arranged with the Piedmont Regional Office. These records shall include, but are not limited to:</p> <p>a. Annual number of cycles, calculated monthly as the sum of each consecutive 12 month period.</p> <p>b. Scheduled and unscheduled maintenance, and operator training.</p> <p>These records shall be available for inspection by the DEQ and shall be current for the most recent five years.</p> <p>(9 VAC 5-80-1180 and 9 VAC 5-50-50)</p>	<p>The facility maintains records of these data and operating parameters as required by the Permit. Please refer to Inspector observation for Condition 5 regarding annual number of ETO sterilizer cycles.</p> <p>Scheduled maintenance is not based on a per cycle basis according to the facility; scheduled maintenance is performed approximately every six months on all pieces of equipment or on an "as needed basis." According to the facility, maintenance records will now be maintained in a notebook together with chart graph recordings and throughputs. The facility provided records indicating operator training as indicated by the attached 'In Service Attendance Sheet' and 'Mandatory In Service-ETO'.</p>	In Compliance
06-10-05	4	<p>Right of Entry - The permittee shall allow authorized local, state, and federal</p>	<p>The permittee allowed the announced inspection to proceed without any</p>	In Compliance



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		representatives, upon the presentation of credentials: a. To enter upon the permittee's premises on which the facility is located or in which any records are required to be kept under the terms and conditions of this permit; b. To have access to and copy at reasonable times any records required to be kept under the terms and conditions of this permit or the State Air Pollution Control Board Regulations; c. To inspect at reasonable times any facility, equipment, or process subject to the terms and conditions of this permit or the State Air Pollution Control Board Regulations; and d. To sample or test at reasonable times. For purposes of this condition, the time for inspection shall be deemed reasonable during regular business hours or whenever the facility is in operation. Nothing contained herein shall make an inspection time unreasonable during an emergency. (9 VAC 5-170-130)	delays or denial of access to any facility location or document.	



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06-10-05	8	<p>Maintenance/Operating Procedures - The permittee shall take the following measures in order to minimize the duration and frequency of excess emissions, with respect to air pollution control equipment and process equipment which affect such emissions:</p> <p>a. Develop a maintenance schedule and maintain records of all scheduled and non-scheduled maintenance.</p> <p>b. Maintain an inventory of spare parts.</p> <p>c. Have available written operating procedures for equipment. These procedures shall be based on the manufacturer's recommendations, at a minimum.</p> <p>d. Train operators in the proper operation of all such equipment and familiarize the operators with the written operating procedures. The permittee shall maintain records of the training provided including the names of trainees, the date of training and the nature of the training.</p> <p>Records of maintenance and training shall be maintained on site for a period of five years and shall be made available to DEQ</p>	<p>A maintenance schedule was made available for the equipment. Scheduled maintenance is not based on a per cycle basis according to the facility; scheduled maintenance is performed approximately every six months on all pieces of equipment or on an "as needed basis." Upon request, the facility provided a copy of a work order identifying work performed on the equipment (See Attachment). According to the facility, maintenance records will now be maintained in a notebook together with chart graph recordings and throughputs. Spare parts are maintained by the ETO sterilizer manufacturer and are provided to the facility on an as-needed basis. Operating book with operating guides for each ETO sterilizer and abators are kept on-site for facility personnel use. Training to operators is provided by the ETO</p>	In Compliance



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		personnel upon request. (9 VAC 5-50-20 E)	sterilizer manufacturer personnel through training sessions termed 'In Services'. According to the facility, In-Services are provided on an as needed / as requested basis. The facility provided records indicating operator training as indicated by the attached 'In Service Attendance Sheet' and 'Mandatory In Service-ETO'. The facility is aware of the requirement to maintain records of training on-site.	
06-10-05	12	Permit Copy - The permittee shall keep a copy of this permit on the premises of the facility to which it applies. (9 VAC 5-170-160)	The NSR Permit was on-site, and the permittee made the permit available to the Inspector upon request.	In Compliance

Andrew,

Good Morning, I have Documentation for the testing and work being done on the Honeywell recording chart to meet the abaters requirements.
Thanks you very much for you help with this.

Item 1: Per Condition 3 of the facility's June 10, 2005 permit, "The operating temperature of the two abaters shall be maintained at a minimum of 400 F when the unit is in operation". During the inspection, no data were available demonstrating compliance with this condition. Accordingly, please provide a narrative describing what actions the facility will take to resolve this compliance item and verification, in the form of a narrative description of temperature readings during operation, that the 400 F condition is being met. Please provide this narrative to VADEQ per the instructions below provided.

I have had the Biomet Department of Bon Secours come and work with Honeywell (Chart Provider) and 3M the makers of the ETO Machines and the Abater

Working together to assure that the Equipment is functioning properly. I have each chart recording as listed below I have been assured that the abaters are

Working properly Attached is a copy of the letters and e-mails. I will also fax.

1. I have abater # 1 Assigned to handle two ETO sterilizers, Sterilizer # One and # Two This chart during the finale phase is reaching the Temperature of Of 370 to 390 F while operating both Sterilizer as the same time.
2. I have the abator # 2 Assigned to handle One ETO sterilizer, Sterilizer # Three This chart during the finale phase is reaching the Temperature of Of 390 to 410 F Item.

Item 2: Per Condition 8 of the facility's June 10, 2005 permit, "d. Train operators in the proper operation of all such equipment and familiarize the operators with the written operating procedures. ". Please provide records of employee training per our on-site

1. I have had all the staff trained by the 3m corp. Per Steve . Also operating instructions are place by the Sterilizers for the staff.
2. Also will fax.

Item 3: I brought this item up with Mr. Dorfman but failed to mention it during the post-inspection meeting, since the Model 20 Aeration Cabinet rated at 0.22 lbs of sterilization compound per cycle is no longer being used, I recommend you contacting Air Permitting and discuss removing the equipment from the current permit. Also, I wanted to pass along a recommendation that St. Mary's remove the 3 ETOs from their current facility permit. If you could forward this request to the appropriate St. Mary's staff I would appreciate it. The St. Mary's permit from 1994 has Mr. Ralph Wheeler's name on it, so I suppose he would be the person to address the permit issue. He and you can contact Mr. Daniel Gaidos (VADEQ Permit Writer) @ 804-527-1227 to process these permit changes

1. I have forwarded you e-mail to Ralph Wheeler to take care of this request.

Please contact me if I need to send or do anything else



Donaldson Abator Abator ETO
Specs_1993.pdf... Efficiency vs Temp...

Scarlett,

I sent you an email earlier. It may have been sending toward you as you were sending this one to me.

I got in contact with corporate on the differences in temps (what the DEQ wants and what we see). Corporate is telling me that the best efficiency for the abator (99.9%) is at 280* F.

When you look at the charts, your abators (both) rise and rest around this temp. Corporate was concerned as to how the DEQ came up with a temp of 400*. I am enclosing two attachments to back this up.

I was at your facility on Tuesday, June 6, 2006 and examined the charts for both abators, reading all three sterilizers, not only present but previous charts. They are both running consistent within the parameters of the manufacture (Donaldson). The graph shows that the temps rise from ambient to just under 300* (normal operating temp). When the gas is being processed the temps rise to just under 400*. With the recording "plus / minus" errors, the temps are well within the prescribed 99.9% efficient range.

Please forward this information to the DEQ along with the enclosed attachment. If they have more questions, please have the DEQ contact me.

(See attached file:

Abator
ETO Efficiency vs Temp.pdf)
Abator
Specs_1993.pdf]

(See attached file: Donaldson

*Thanks
Scarlett*

When you were born, you were crying and everyone around you was smiling.
Live your life so at the end,
you're the one who is smiling and everyone around you is crying.

Scarlett Mitchell CRCST
Administrative Director Central Sterile
Bon Secours Richmond Health System
804-545-4260(office)
804-545-4265(fax) Pager 287-7725 (0178)
Scarlett_Mitchell@bshsi.com

Donaldson Model 50 SCFM Abator

Abator Permit Data

Equipment description:	The ETO Abator system is an engineering control device for removing ethylene oxide exhausted from the 3M Steri-Vac sterilizer system. The abator converts ethylene oxide to CO ₂ and H ₂ O vapor.
Raw material:	100% EO, 3.54 oz./cycle, 100 grams
Finished product output:	Carbon dioxide and water vapor
Flow rate from sterilizer exhaust to abatement system:	
Batch volume:	3.54 oz. (per sterilization cycle)
Continuous process:	N/A.
Abator exhaust flow rate:	50 SCFM (standard), 60 SCFM maximum
Abator exhaust output temperature:	
Normal:	
Operating:	390-430°F (199°C - 221°C)
Standby:	300-315°F (149°C - 157°C)
Maximum:	500°F (260°C)
Abator Moisture Content:	
Normal:	50%
Maximum:	90%
Abator stack construction material:	Galvanized steel or stainless steel or aluminized steel
Sampling port availability:	Yes (in abator)
Abator operating pressure drop range:	1.5" HG maximum
Abator maximum inlet gas flow:	.017 lbs/min. (0.27202/min = 7.7gr/min)
Abator maximum inlet gas temperature:	131°F (55°C)
Abator efficiency:	99.9%
Abator inlet pollutant concentration:	~3000 ppm
Area heat radiates rate:	1500 BTU/hour or 4.5 KVA/hour
Power consumption:	6.6 KVA
Upstream gas concentration:	
Input:	~3000 ppm
Down stream gas concentration:	
Output:	~3 ppm = 99.9% efficiency
Service plan:	Only if under 3M P.M.A. contract
Frequency:	Every 6 months
Checks:	Temperature, Air flow, efficiency



Health Care

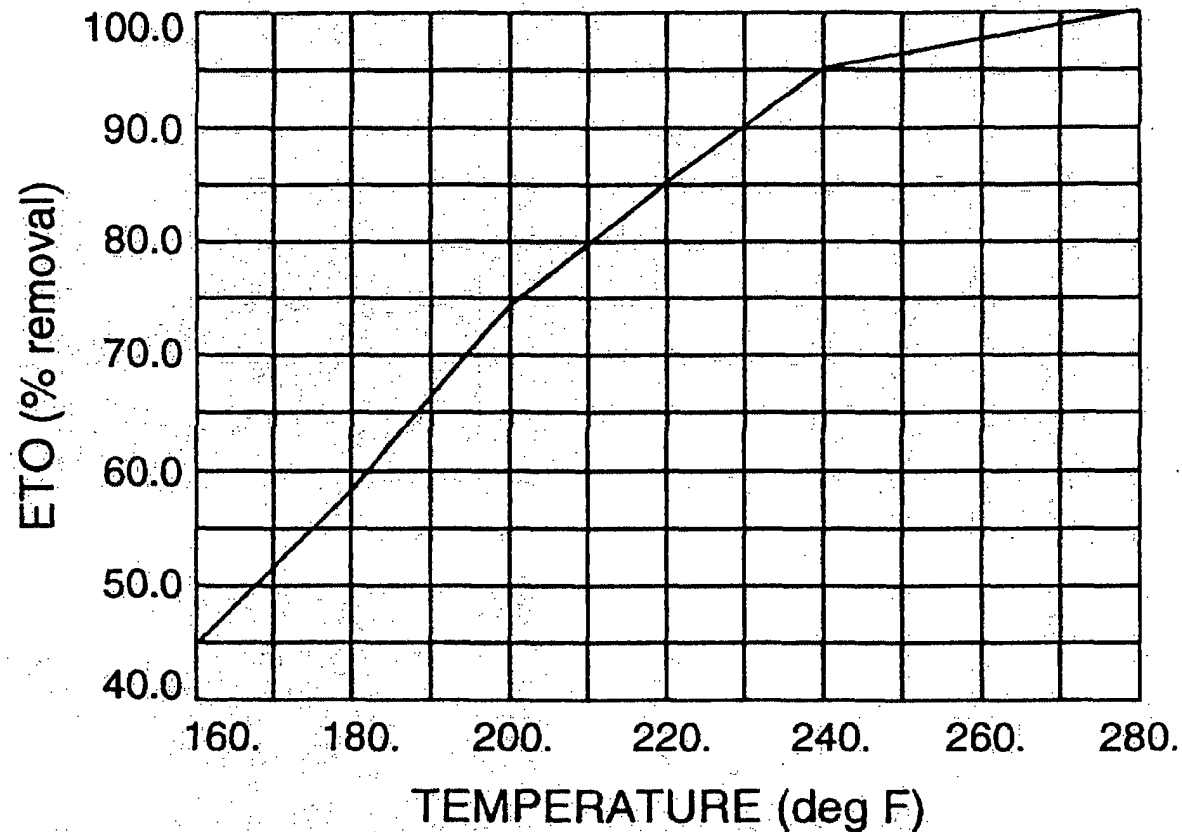
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
1-800-228-3957

ETO-Abator System Model 50 SCFM is a trademark of Donaldson Company.
Steri-Vac is a trademark of 3M.

© 3M 1993 70-2008-6029-7

ETO Conversion Performance

ETO (% removal) vs. TEMP (deg F)



3M Internal Correspondence

Date: 27-Jun-1997 10:31am CTZ
From: HALL, DARRELL
HALL, DARRELL
Dept: Infection Control
Tel No: 800-688-5888, Ext. #8816

TO: Distribution not printed

Subject: Chart Recorder info

Gentlemen,

Regarding Daves memo concerning the installation and setup of the Honeywell Chart recorder for use with abators, some information:

Type J thermocouple wire: the positive input lead has iron in it (ergo:magnetic so use your magnetic screwdriver to identify the plus (+) input wire. If the abator is farther from the recorder than the dual RTD lead will reach, Type J extension wire can be purchased thru wire suppliers. Soldering is'nt practical, a good, tight mechanical splice is sufficient.

Recorder setup recommendations (section 4.4):

Chart speed7 days (saves charts)

Time Div.....default

Chart name....."abator" (so whoever looks at it will know where its from)

Header.....Yes (prints graph parameters, chart name, date at start of recording)

Recorder setup recommendations (section 4.6):

Chart1HI to 500 (if we go higher than that, we know we got problems)

Chart1LO to 250 (the unit won't work below this temp anyway)

MAJORDIV to 5

MINORDIV to 5

These will give a chart printout that is less "busy" and easier to read. When adjusting the settings, you use the UP and DOWN arrows to adjust each parameter. You can jump to to next higher digit by pressing the opposite arrow (e.g.. you want to change the temp setting up. You press the UP arrow and the tenths digit increases. While holding down the Up arrow, press the DOWN arrow till the ones digit is changing. Press the DOWN arrow again to jump to tens and also hundreds. The reverse is true for going in the opposite direction

As far as accuracy is concerned I have seen variations from the recorder to my temp probe in the airstream of 6 to 25 degrees higher. Since the purpose of the recorder is to satisfy the local air quality board inspectors that the number of loads being burned is the same as the number of carts used and a suitable burn temp is being achieved, accuracy is not paramount. But for my own benefit, I usually will monitor the air stream with my temp probe and adjust the INPUT1 compensation so that it gets what I measure, and whats displayed, at least close.

**INSTALLATION OF
RTD/TC IN CHART RECORDER AND ABATOR**

THE CONTRACTOR IS TO MOUNT THE CHART RECORDER PER THE MANUAL PROVIDED WITH IT, AND RUN 3/4" CONDUIT FROM THE SIDE OF THE ABATOR WITH THE INLET, EXHAUST, AND EO INLET.

THE RTD/TC SUPPLIED BY DONALDSON HAS A 25' LEAD WHICH SHOULD BE CONNECTED TO THE CHART RECORDER PER THE MANUAL INSTRUCTIONS. THE CHART RECORDER SHOULD BE MOUNTED ACCORDINGLY. THE RTD/TC PROBE SHOULD BE INSTALLED IN PLACE OF THE RTD IN THE WELDMENT WHICH FEEDS INTO THE BLOWER.

THE LEADS TERMINATED WITH GOLD SOCKETS MUST BE INSERTED IN THE LARGER CONNECTOR, J2, IN HOLES 24 AND 25.

4500 CHART RECORDER SET-UP

BEFORE MOUNTING YOUR RECORDER, READ THE APPLICATION NOTES LOCATED BETWEEN CHAPTERS 3 & 4 OF THE DR 4500 PRODUCT MANUAL.

1. MOUNT THE RECORDER PER SECTION 2.
2. INSTALL YOUR 120 VAC OR 240 VAC POWER PER SECTION 3A, PAGE 3-1.
3. CONNECT YOUR T/C LEADS PER SECTION 3B ON PAGE 3-2.
4. PROCEED TO PAGE 4-31 TO SET UP YOUR RECORDER AND PERFORM STEPS 1 THROUGH 14 SKIPPING STEPS 4 AND 5.

BELOW ARE HINTS FOR SPECIFIC STEPS.

D-2 CUSTOMER OPTION
D-8 SET TO SAME NO. OF DIVISIONS AS YOU CHOOSE IN STEP 2. e.g., 8 HR WORKS WELL WITH 8 DIVISIONS.
D-10 CUSTOMER OPTION. e.g., "ABATOR RUNS".
D-13 CHOOSE NONE

5. PROCEED THROUGH SECTION E AND INTO F, SKIPPING F10, 11, 12, AND 13.

F-6 ENTER 600
F-8 ENTER 0
F-14 SELECT 8
F-16 SELECT 10
F-18 ENTER TEMPI, THEN RTD2 FOR RANGE TAG.

6. PROCEED THROUGH SECTION G, SKIPPING G-10 AND 11.

G-4 SELECT DEG F
G-6 ENTER DEG F
G-8 ENTER JTCH
G-12 ENTER 600
G-14 ENTER 0
G-20 SELECT NONE

REVIEW OPERATION AND MAINTENANCE, SECTION 5 AND CALIBRATION, SECTION 8

P195779

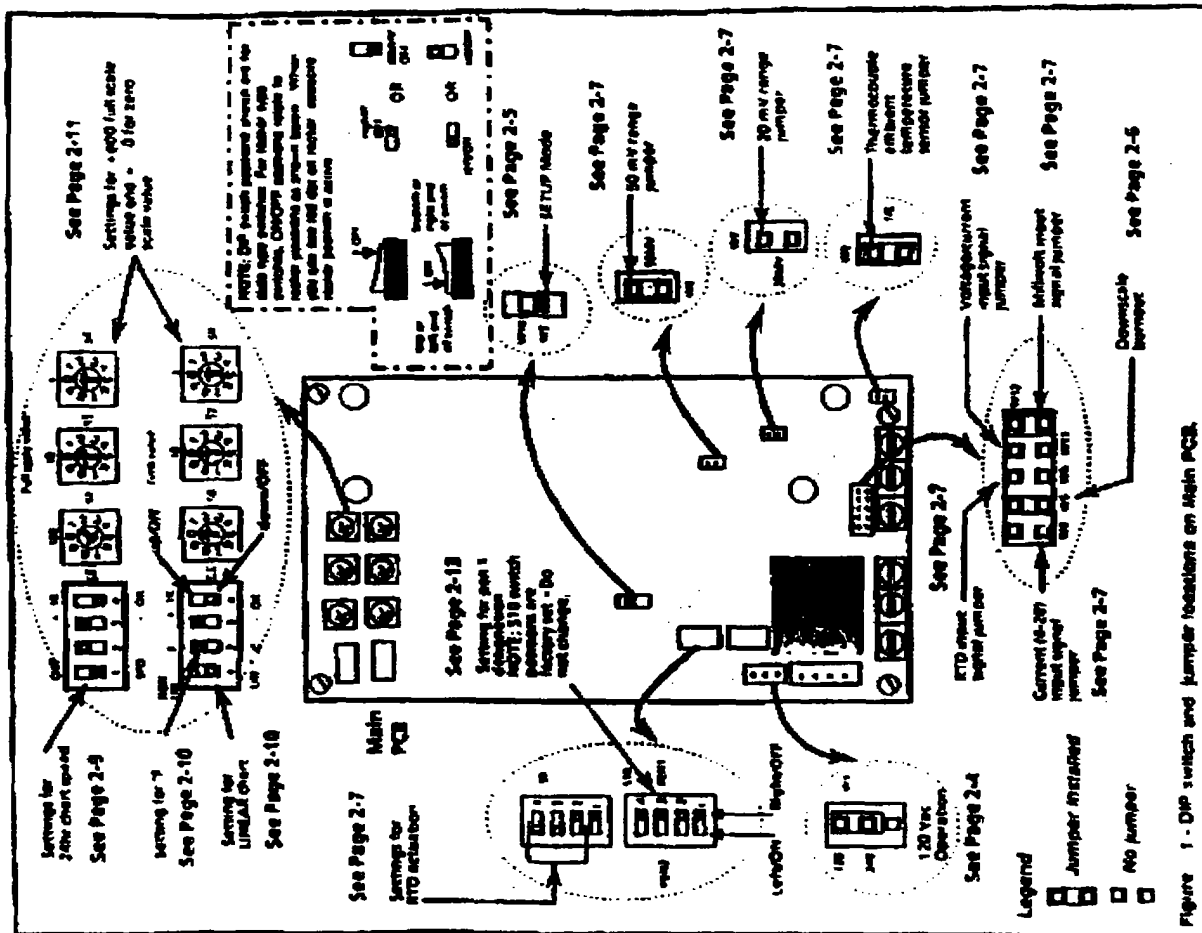


Figure 1 - DIP switch and jumper locations on Main PCB.

MATERIAL		RELEASE NO. 94A5740		TITLE	
		DATE MAY 25, 1994		4200 CHART RECORDER	
		EXP DATE MAR 7, 1994			
		DWN T. FEDDERSEN		NUMBER	
REFERENCE KYN006556		DATE MAY 25, 1994		P196197	
		CHK			
		DATE		SCALE NONE	
PREVIOUS DRAWING NO.		APVD		SHEET 20F 2	
		DATE		C/C **	
DO NOT SCALE		TOLERANCES UNLESS OTHERWISE SPECIFIED		CADD	
2 F.L.		3 PL.		SECTIONAL SIZE X	
ANGLES		THIRD ANGLE PROJECTION		OUTLINE SIZE NO	
				DESIGN CONTROL A 023 DRWG LOCATION A 100 VERSION A	
				All rights to manufacture, copy, reproduce, or dispose of this drawing or its contents are reserved unless otherwise specified in writing by Donaldson Company, Inc.	
				L B	



Ethylene Oxide Sterilization Record St. Mary's Hospital

ACMI Cystoscope
Amb Surgery
Anesthesia
ARW ARC
Amp Knife
AUR 7 Flexible Scope
AUR 9 Flexible Scope
Boskinsky Forceps
Banding Gun (Heart)
Brain Lab Tray
Breast Retractors
Chole Nephroscope Tray
Cholodoscope Tray
CCU Cords (Pacemaker)
Cysto Cords
Cosgrove Retractor
CVICU Cords
CT Halo
Cath Lab Cords (pacemaker)
Dr. Kriesler Needle Probe
Dr. Wares Dilators
Dr Graham Instruments
Dental Rubber Bands
Dental Wire
Defib Paddles (Heart)
Doppler cords
Endo Bottles
Eye Instruments (ambulatory)
External Pedi Defib Paddles
Endo Cords (General)
Endo Facial Tray
FilForms and Followers
Glass Slides
Genzyme System
Genzyme Fiberoptic Cord
Genzyme Handle (Gold)

Versapoint Hysterscope ①

Harrison Inst
Heart Fiberoptic Cords
Heart Bandages
Heart Valve Sizers
ICU Cords (Pacemaker)
Infant Cystoscopes
Jed Med Drill
Laser Fiber (Cysto)
Laryn Mirrows
Kleppinger Bi-Polar & Cord
Mag Pad (Heart)
Mag Pad (Neuro)
Micro Inst. (Extra Heart)
Mediastinscopy Tray
Mouth Pieces (Resp Therapy)
Nasal Snare ENT
Nebulizer Rt
OR Spray Bottle
Ortho Cords
Ortho Camera
Ortho 30 Scope
Pacemaker Cords
Pacu Adapter
Pedi Cystoscopes
Pedi Resectoscope Tray
Percutaneous Tray
Radition Therapy
Resp. Therapy (Extras)
Signoidscope Tray
Skeeter Drill
Straight Shot Drill
Steriotactic Tray
Sternal Saw (Heart)
St Mark's Retractor
Tyson Forcep
Ultra Sound Probes (Cysto)

3
2

Bugbee ①

①

Date 5-18-04

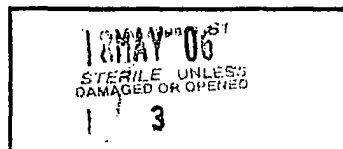
Load No. 1

Cycle warm / cold

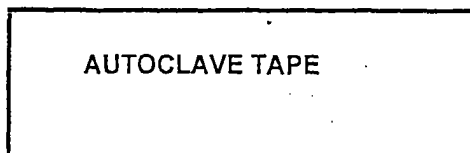
Sterilizer No. 3

Time 4:08 AM & PM

Total Items 19



Dr. Winslow wdf scope ⑩
light cords



Initial SB/VB

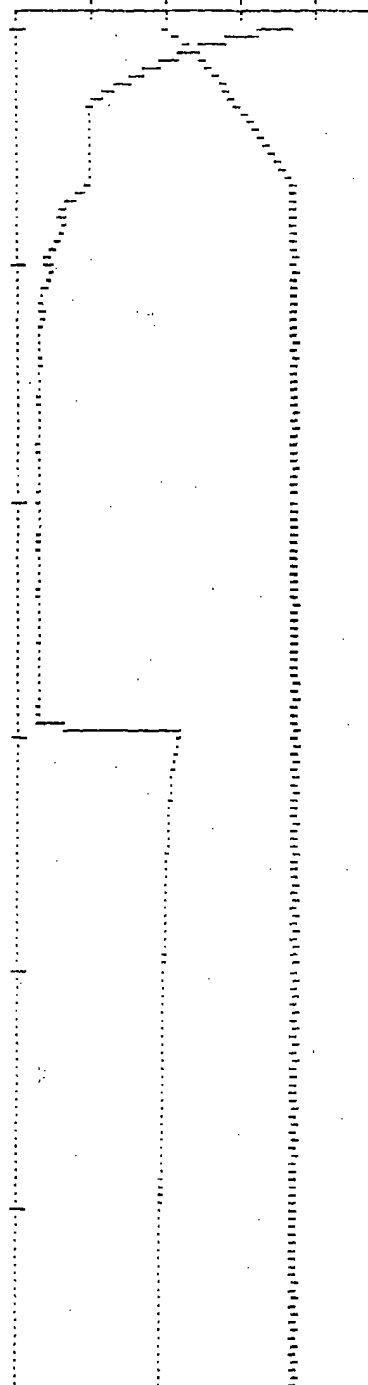
18 MAY 06
STERILE UNLESS
DAMAGED OR OPENED

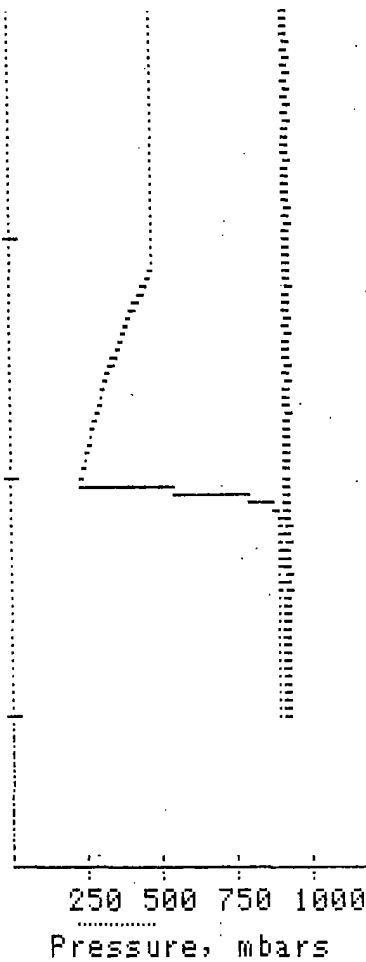
1 3

3M STERI-VAC
ETO STERILIZER

DATE:
LOAD#:
CYCLE#: 2930
55 °C CYCLE SELECTED

TEMP: °C
15 30 45 60





EXPOSE TIME: 01:02

DOOR OPENED: 00:18

AERATE TIME: 12:22

NO ERRORS
NO CAUTIONS

NOTES:

Checked by: -----

St. Mary's Hospital

Genzyme Handle (Gold)

Total Items 13

Ent Sur Track

Ultra Sound Probes (Cysto)

Here Sandbag

1 MAY 05
STERILE UNLESS
DAMAGED OR OPENED

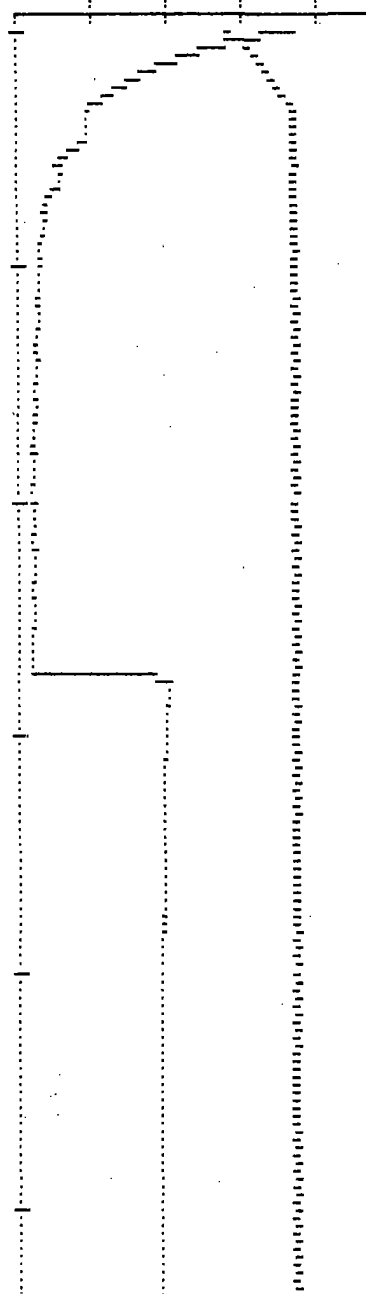
3

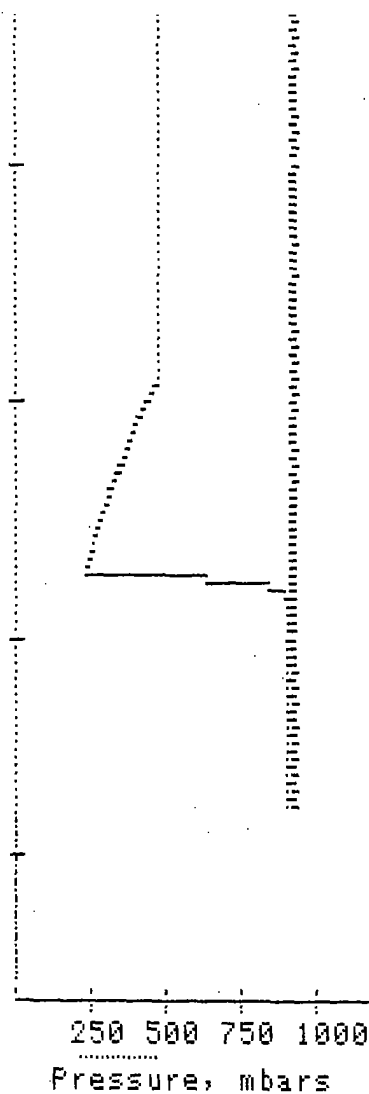
3M STERI-VAC
Eto STERILIZER

DATE:
LOAD#:
CYCLE#: 2933
55 °C CYCLE SELECTED

TEMP, °C

15 30 45 60





EXPOSE TIME: 01:02

AERATE TIME: 00:49

NO ERRORS
NO CAUTIONS

NOTES:

Checked by: -----

DOCUMENT CERTIFICATION

Facility Name: Central Virginia Health Network

Registration No. 52111

Facility Location: 2521 Brittons Hill road Richmond, Va

Type of Submittal Attached: Abaters, Education, Training

Certification: I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering and evaluating the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Name of Responsible Official (Print): Scarlett Mitchell

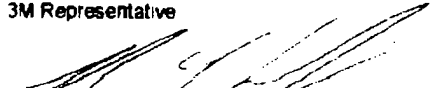
Title: Admin. Director Sterile Processing

Signature:  Date: 06/09/06

3M Health Care Service Center
Suite 200, Building 502
3350 Granada Ave
Oakdale, MN 55128

Name Central Sterile Off-Site	Date of Inservice 5/23/06	
Address 2521 Brittons Hill Road	Model (if applicable) 4XL / XL / 50A	Serial Number (if applicable) multiple
City, State, Zip Richmond, VA 23230	Dept. Name Sterile Processing	
Phone Number 804 545-4260	Ext	Dept Supervisor/Manager Scarlett Mitchell
E-Mail Address scarlett_mitchell@bshs.com		

610

Name (Please Print)	Name (Please Print)
NATASHA Johnson	
Shawonda Johnson	
Jane Opie Brown	
CHRIS GRAVES	
Tonya Tabb	
Paul Clarke	
Shelby Belcher	
Rosalind Williams	
Redie Smith	
Elizabeth Edwards	
Regina Jones	
Lisette Freeman	
Reginald Brown	
Shawn Mitchell	
3M Representative	Customer Signature
	Scarlett Mitchell

Mandatory
In Service - ETO
2pm

BON SECOURS RICHMOND HEALTH SYSTEM
DIVISION OF SURGICAL SERVICES/CENTRAL STERILE
INSERVICE/STAFF MEETING MINUTES

DATE: 11/11/06

Participants: Judy Adkins _____, Marquita Alston _____, Vincent Battle VB, Shelby Belcher SB,
 Jane Opie Brown JOB, Clarke, Paul PC, Duncan, Reginald, RD, Mable Jones _____,
 Edwards, Elizabeth EB, Footman, Lucille LF, Harvey, Joann HJ,
 Hill, Cynthia _____, Johnson, LaChanda _____, Johnson, Natosha NJ,
 Mines, Evangeline _____, Mitchell, Scarlett _____, Smalls, Louise _____,
 Smith, Leslie LS, Tabb, Tanya TT, Williams, Rosalind RW, Young, Regina RY ATIS GRAVES AG

TOPIC	DISCUSSION	OUTCOME/ACTION REQUIRED
In Service Meeting: <u>ETO Sterilizer</u>		
Given by: <u>Shirley Durham</u>		
Subject:		



**Customer
Service Order**

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179064

Date Served	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	4XL	522860		PMA Sch 2

Customer	VKZ4806	Bill To	QDB6363
Name	ST MARY HOSPITAL	Name	ARAMARK CTS
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269

Description of Work Performed	Qty	Stock	Price	Amount
Kit, Tune Up	1	78-8055-6319-0	\$675.75	\$675.75
Spring, Door	1	26-1000-8519-5	\$5.90	\$5.90
Setscrew 8-32 x 1/8L	2	18-3402-7075-2	\$1.80	\$3.60
Solenoid Valve, Vent	1	12-2376-9138-6	\$183.80	\$183.80
kit, door handle & shaft	1	78-8069-7636-7	\$467.40	\$467.40
Controller Board (R)	1	78-8055-5900-8	\$1,466.70	\$1,466.70

Total Parts	\$2,803.15
Labor Charge 6.0 Hrs. @ \$255.00	\$1,530.00
Travel Charge 3.0 Hrs. @ \$215.00	\$645.00
Sub Total	\$4,978.15
Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

All Required Fac. Mods current [X], Final Check per Service Bulletin 48 [X], Hood Flow Sensor [X]
User Interruption [X], Cold Temperature Abort [X], Door Open [X]
No Gas Abort [X], C/Cold Temperature [37° C], C/Warm Temperature [55° C]
M Bars Dead End Vacuum [64 mBars], Mins. Initial Pump Down Time [5 min], MBars Hi Pres. Chamber Leak test in 10 Minutes [0.00]
ml Moisture Injection [10 ml], All Required Fac. Mods current [X], Equipment Inservice Given Y/N [Y]
EO Inservice Given Y/N [Y], Service Switches Normal [X]

Service Technician Dorfman, Steve	Customer Name Scarlett Mitchell
---	---

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH SPECIFICATIONS PUBLISHED BY 3M.



Customer Service Order

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179057

Date Served	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	4XL	522861		PMA Sch 2
Customer	VKZ4806	Bill To	QDB6363	
Name	ST MARY HOSPITAL	Name	ARAMARK CTS	
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK	
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Kit, Tune Up	1	78-8055-6319-0	\$675.75	\$675.75
Spring, Door	1	26-1000-8519-5	\$5.90	\$5.90
Setscrew 8-32 x 1/8L	2	18-3402-7075-2	\$1.80	\$3.60
Controller Board (R)	1	78-8055-5900-8	\$1,466.70	\$1,466.70
Solenoid Valve, Door	1	12-2376-9143-6	\$208.30	\$208.30
Switch, Interlock, Modified	1	78-8078-5873-9	\$34.60	\$34.60
Water cap, Silkscreened	1	78-8078-2947-4	\$7.00	\$7.00

Total Parts	\$2,401.85
Labor Charge	\$1,530.00
Travel Charge	\$645.00
Sub Total	\$4,576.85
Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PMComplete
All Functions Ck-OK

Field Data

All Required Fac. Mods current [X], Final Check per Service Bulletin 48 [X], Hood Flow Sensor [X]
User Interruption [X], Cold Temperature Abort [X], Door Open [X]
No Gas Abort [X], C/Cold Temperature [37* C], C/Warm Temperature [55* C]
M Bars Dead End Vacuum [056 mBars], Mins. Initial Pump Down Time [5 min], MBars Hi Pres. Chamber Leak test in 10 Minutes [0.00]
ml Moisture Injection [10 ml], All Required Fac. Mods current [X], Equipment Inservice Given Y/N [Y]
EO Inservice Given Y/N [Y], Service Switches Normal [X]

Service Technician	Customer Name
Dorfman, Steve	Scarlett Mitchell

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH
SPECIFICATIONS PUBLISHED BY 3M.



Customer Service Order

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179056

Date Serviced	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	4XL	522152		PMA Sch 2
Customer	VKZ4806	Bill To	QDB6363	
Name	ST MARY HOSPITAL	Name	ARAMARK CTS	
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK	
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Kit, Tune Up	1	78-8055-6319-0	\$675.75	\$675.75
Spring, Door	1	26-1000-8519-5	\$5.90	\$5.90
Setscrew 8-32 x 1/8L	2	18-3402-7075-2	\$1.80	\$3.60
Valve, Solenoid	1	78-8078-6778-9	\$221.10	\$221.10
E.O. Monitor Badge, #3550	2	12-2376-7972-0	\$40.25	\$80.50

		Total Parts	\$986.85
Labor Charge	6.0 Hrs. @	\$255.00	\$1,530.00
Travel Charge	3.0 Hrs. @	\$215.00	\$645.00
		Sub Total	\$3,161.85
		Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

All Required Fac. Mods current [X], Final Check per Service Bulletin 48 [X], Hood Flow Sensor [X]
User Interruption [X], Cold Temperature Abort [X], Door Open [X]
No Gas Abort [X], C/Cold Temperature [37° C], C/Warm Temperature [55° C]
M Bars Dead End Vacuum [040 mBars], Mins. Initial Pump Down Time [5 min], MBars Hi Pres. Chamber Leak test in 10 Minutes [0.00]
ml Moisture Injection [10 ml], All Required Fac. Mods current [X], Equipment Inservice Given Y/N [Y]
EO Inservice Given Y/N [Y], Service Switches Normal [X]

Service Technician	Customer Name
Dorfman, Steve	Scarlett Mitchell

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Customer Service Order

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179058

Date Serviced	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	50A	3496571		PMA Sch 2
Customer	VKZ4806	Bill To	QDB6363	
Name	ST MARY HOSPITAL	Name	ARAMARK CTS	
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK	
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Prefilter, Modified	1	78-8078-9728-1	\$61.00	\$61.00
Kit, Repair norm/open Solenoid M-50	1	26-1009-9647-4	\$159.40	\$159.40
Kit, Repair, norm/closed Solenoid M-50	1	26-1009-9646-6	\$122.80	\$122.80
Indicator Bulb, M-50	3	78-8069-7440-4	\$12.90	\$38.70

			Total Parts	\$381.90
Labor Charge	3.5	Hrs. @	\$255.00	\$892.50
Travel Charge	3.0	Hrs. @	\$215.00	\$645.00
			Sub Total	\$1,919.40
			Total Charges	\$0.00

Customer Input: Sch POM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

Check Low Air Flow Light [X], All Required Factory Modifications Incorporated [X], C Temp W/Ready Light On [129.6° C]
CFM Air Flow at Ready [68.7 CFM]

Service Technician	Customer Name
Dorfman, Steve	Scarlett Mitchell

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH SPECIFICATIONS PUBLISHED BY 3M.



Customer Service Order

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179065

Date Serviced	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	50A	3496572		PMA Sch 2
Customer	VKZ4806	Bill To	QDB6363	
Name	ST MARY HOSPITAL	Name	ARAMARK CTS	
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK	
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Prefilter, Modified	1	78-8078-9728-1	\$61.00	\$61.00
Kit, Repair norm/open Solenoid M-50	1	26-1009-9647-4	\$159.40	\$159.40
Kit, Repair, norm/closed Solenoid M-50	1	26-1009-9646-6	\$122.80	\$122.80
Indicator Bulb, M-50	3	78-8069-7440-4	\$12.90	\$38.70

			Total Parts	\$381.90
Labor Charge	3.5	Hrs. @	\$255.00	\$892.50
Travel Charge	3.0	Hrs. @	\$215.00	\$645.00
			Sub Total	\$1,919.40
			Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

Check Low Air Flow Light [X], All Required Factory Modifications Incorporated [X], C Temp W/Ready Light On [137.3° C]
CFM Air Flow at Ready [93.3 CFM]

Service Technician	Customer Name
Dorfman, Steve	Scarlett Mitchell

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH SPECIFICATIONS PUBLISHED BY 3M.



**Customer
Service Order**

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179068

Date Serviced	Model Type	Serial Number	Customer PO#	Type of Call
5/19/2006	XL	101499		PMA Sch 2
Customer	VKZ4806	Bill To	QDB6363	
Name	ST MARY HOSPITAL	Name	ARAMARK CTS	
Address	5801 BREMO ROAD	Address	ACCOUNTS PAYABLE 10510 TWIN LAKES PARK	
City, State, Zip	RICHMOND, VA, 23226	City, State, Zip	CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Filter, Bacterial	2	78-8055-5905-7	\$137.70	\$275.40

			Total Parts	\$275.40
Labor Charge	2.0	Hrs. @	\$255.00	\$510.00
Travel Charge	3.0	Hrs. @	\$215.00	\$645.00
			Sub Total	\$1,430.40
			Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

All Required Factory Modifications Incorporated [X], Cold Temperature [35.7° C], Warm Temperature [53.8° C]
Exhaust Blower Checked [X], Inches H2O negative static pressure [-0.30"], Internal Blowers Checked [X]
Timer Times to Cycle Complete [X]

Service Technician
Dorfman, Steve

Customer Name
Scarlett Mitchell

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH
SPECIFICATIONS PUBLISHED BY 3M.



**Customer
Service Order**

3M Health Care
Suite 200 Bldg 502
3350 Granada Ave N
Oakdale, MN 55128

Service Order No.
000000000179062

Date Serviced 5/19/2006	Model Type XL	Serial Number 101498	Customer PO# QDB6363	Type of Call PMA Sch 2
Customer Name ST MARY HOSPITAL	Address 5801 BREMO ROAD	City, State, Zip RICHMOND, VA, 23226	Bill To Name ARAMARK CTS	Address ACCOUNTS PAYABLE 10510 TWIN LAKES PARK
			City, State, Zip CHARLOTTE, NC, 28269	

Description of Work Performed	Qty	Stock	Price	Amount
Filter, Bacterial	2	78-8055-5905-7	\$137.70	\$275.40

		Total Parts	\$275.40
Labor Charge	2 Hrs. @	\$255.00	\$510.00
Travel Charge	3 Hrs. @	\$215.00	\$645.00
		Sub Total	\$1,430.40
		Total Charges	\$0.00

Customer Input: Sch PM #2 Due BPA

Problem Found: No Problems Found

Solution: Sch PM Complete
All Functions Ck-OK

Field Data

All Required Factory Modifications Incorporated [X], Cold Temperature [36.5* C], Warm Temperature [54.2* C]
Exhaust Blower Checked [X], Inches H2O negative static pressure [-0.30"], Internal Blowers Checked [X]
Timer Times to Cycle Complete [X]

Service Technician
Dorfman, Steve

Customer Name
Scarlett Mitchell

THIS SHALL CERTIFY THAT THIS DEVICE HAS BEEN INSPECTED AND TESTED IN ACCORDANCE WITH SPECIFICATIONS PUBLISHED BY 3M.